K090943

5 510(k) Summary

MAY 27 2009

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter:
American Biological Technologies, Inc.
940 Crossroads Blvd
Seguin, TX 78155
(830) 372-1391 ex. 210
Establishment Registration Number: 1643621

Contact Person:
John C. Gormley
American Biological Technologies, Inc.
940 Crossroads Blvd
Seguin, TX 78155
(830) 372-1391 ex. 210

Device Name: AbT Glucose Control Solution

Common Name: Single Analyte Control Solution, All Types (Assayed and Unassayed)

Classification Name: Quality Control Material (assayed and unassayed).

Classification: Class I per 21 CFR 862.1660

Product Code: 75 JJX

Panel: Chemistry

Predicate Devices:

Name:	WaveSense Normal Control Solution
Manufacturer:	AgaMatrix, Inc.
510(k) No.:	K052762
Name:	Liberty Normal Control Solution
Manufacturer:	Liberty Healthcare Group, Inc.
510(k) No.:	K063855

Device Description: The AbT Glucose Control Solution consists of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of glucose. It is

packaged in a plastic dropper tipped bottle for easy application of the control solution to the test strips and a red coloration to aid the user to visually confirm application of the control. The product is non-hazardous and contains no human or animal derived materials.

Intended Use:

The AbT Glucose Control Solution is intended for in vitro diagnostic use by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the WaveSense Presto Blood Glucose Monitoring System.

Comparison to Predicate Device:

Characteristic/ Aspect	Predicate Device No. 1	Predicate Device No. 2	New Product
Name	WaveSense Normal Control Solution	Liberty Normal Control Solution	AbT Glucose Control Solution
510(k), Date	K052762, 01/23/2006	K063855, 02/01/2007	
Number of Levels	1	1	1
Analytes	Glucose	Glucose	Glucose
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper tip	Plastic bottle with dropper tip
Fill Volume	6 mL	3.6 mL	3.6 mL
Color	Blue	Red	Red
Target	108 – 159[(1)]	94 – 147[(2)]	95 – 145
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solutions of D-Glucose, viscosity modifiers, preservatives, and other non-reactive ingredients	Buffered aqueous solutions of D-Glucose, viscosity modifiers, preservatives, and other non-reactive ingredients
Indications for Use	Used with the WaveSense-enabled Blood Glucose Meter and WaveSense Test Strips to ensure that the meter and test strips are working together properly.	Used to check the performance of Liberty Blood Glucose Monitoring System.	Used to check the performance of AgaMatrix WaveSense Presto Glucose Monitoring System.
Target Population	Professional and home use	Professional and home use	Professional and home use

[(1)]Estimated from WaveSense Presto test strip lots published ranges.

[(2)]Estimated from Liberty Normal Control Solution published control ranges.

Performance Studies: Tests were performed to verify specific performance characteristics:

1. Stability
2. Open Vial Stability
3. Test precision

Conclusion: Comparison of the performance characteristics, formulation and intended use support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 27 2009

American Biological Technologies, Inc.
c/o Mr. John Gormley
Director of Quality and
Regulatory Affairs
940 Crossroads Blvd.
Seguin, TX 78155

Re: k090943
Trade/Device Name: AbT Glucose Control Solution
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Code: JJX
Dated: May 5, 2009
Received: May 11, 2009

Dear Mr. Gormley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K090943

Device Name: AbT Glucose Control Solution

Indications For Use:

For in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Agamatrix WaveSense Presto Blood Glucose Monitor.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K090943